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EXAMINER

SILVER, DAVID

ART UNIT PAPER NUMBER

2128

DATE MAILED: 09/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/040,373

Applicant(s)

BRAZHNIK ET AL.

Examiner

David Silver

Art Unit

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/3/06, 6/13/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-28 were originally presented for examination.
2. Claims 1-28 were rejected.
3. Claims 1-38 are currently pending in Instant Application.
4. The Instant Application is not currently in condition for allowance.

Information Disclosure Statement

5. The information disclosure statement(s) (IDS) submitted on 6/13/06 is not in compliance with 37 CFR 1.97 and was not considered. The art does not qualify as prior-art and therefore will not be considered.
6. The IDS submitted on 7/03/06 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement(s) is/are being considered by the examiner.

Response to Arguments

7. Applicant's arguments with respect to claims 1-28 have been considered but are moot in view of the new ground(s) of rejection as necessitated by amendment.
- 7.1 Independent claims 1, 7, 10, 16, 20, and 24 now recite a new limitation "wherein the simulation comprises a representation of two macronutrient metabolisms selected from the group consisting of fat metabolism, protein metabolism, and carbohydrate metabolism".
- 7.2 Independent claims 25, 27 now further limit that the simulation comprises representation of fat metabolism. The claims as recited now change the scope of the claimed invention when compared to the previously presented claims. The previous version of the claims had at least one biological attributes of diabetes in context of fat metabolism.
- 7.3 Independent claims 26, 28 now further limit that the simulation comprises representation of protein metabolism. The claims as recited now change the scope of the claimed invention when compared to the previously presented claims. The previous version of the claims had at least one biological attributes of diabetes in context of protein metabolism.
- 7.4 Furthermore, Applicants have further clarified the record by stating that "simulation" is used to mean

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the numerical or analytical integration of a mathematical model.

These amendments necessitate new grounds of rejections. Furthermore, Applicants have submitted an IDS statement on 7/3/06, which prompted a new ground of rejections.

Response: Claim Objections

8. Claim objections of claims 10, 16, and 20 withdrawn. Applicants are thanked for the amendments overcoming the deficiencies.

Response: 35 USC 112

9. Applicants have stated on the record that the term "simulation" is used to mean the numerical or analytical **integration** of a **mathematical model**. The 35 USC 112 rejection has been withdrawn in view of arguments made on page 14 of Remarks dated 6/13/06 ("Remarks"). In view of the arguments, the term "representing", "representation" and their functional equivalents are interpreted as a mathematical function to be integrated.

Response: 35 USC 102 / 103 Rejections

10. The Applicants have amended all independent claims in response to an applied art rejection. The amendments necessitate new grounds of rejection. See section titled "Response to Arguments" above.

Duplicate Claims

11. Applicant is advised that should claim 13 be found allowable, claim 14 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

As interpreted in Office Action dated 8/10/05 page 20, the term "similar" means not identical. Thus similar means different. Applicants have been silent in response and therefore have acquiesced by their silence. Therefore, claim 13 and 14 are duplicates.

Claim Interpretation

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12. Applicants have stated on the record that the term "simulation" is used to mean the numerical or analytical **integration** of a **mathematical model**. In view of the arguments, the term "representing", "representation" and their functional equivalents are interpreted as a mathematical function which is integrated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1-9, 24, and 29-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Porumbescu **(US 6,582,366)**.

Porumbescu discloses claim 1: A method for creating a computer model of diabetes, comprising: identifying data relating to diabetes, the data relating changes in biological states to biological attributes of diabetes **(col: 6 line: 5-9, col: 1 line: 41-45);**

identifying a plurality of biological processes related to the data, the plurality of biological processes defining at least one portion of the disease state of diabetes **(col: 7 line: 1-12; col: 1 line: 41-45; col: 4 line: 46: parameters of interest);** and combining the plurality of biological processes to form a simulation of glucose metabolism, wherein the simulation comprises a representation of two macronutrient metabolisms selected from the group consisting of fat metabolism, protein metabolism and carbohydrate metabolism **(col: 9 line: 20-27; col: 7 line: 26-31; col: 6 line: 25-29; col: 5 line: 36-38; col: 5 line: 64-67; col: 2 line: 35-40; Fig 3 and text which further expands on its features with emphasis on time course).**

Porumbescu discloses claim 2: The method of claim 1, further comprising: producing a simulated biological attribute associated with at least one biological attribute of diabetes from the combined

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plurality of biology processes based on the combined plurality of biology processes (**col: 4 line: 49-57; col: 6 line: 42-56; col: 4 line: 66 to col: 5 line: 49 with emphasis on col: 5 line: 10-14**);

comparing the simulated biological attribute with a corresponding biological attribute associated with a reference pattern of diabetes (**col: 5 line: 10-14. The comparison is made when indication such as "heads up" and "in or out of control" are presented to the user. These indications are based on the reference points of diabetes and compared to the simulated values.**); and

identifying the computer model as a valid computer model of diabetes if the simulated biological attribute is substantially consistent with the biological attribute associated with a reference pattern of diabetes (**col: 4 line: 49-57; col: 5 line: 10-14; Figure 2 item "COMPARISON" and text which further expands on the figure's features**).

Porumbescu discloses claim 3: The method of claim 1, wherein the combining the plurality of biological processes includes: forming a first mathematical relation among biological variables associated with a first biological process from the plurality of biological processes (**Fig 2 item "MATHEMATICAL MODEL" and text which further expands on the figure's features; Fig 4; col: 7 line: 54 to col: 8 line: 9 I(t)**); and

forming a second mathematical relation among biological variables associated with the first biological process and a second biological process from the plurality of biological variables associated with the plurality of biological processes (**col: 8 line: 18-30 PE(t); col: 7 line: 13-31 EG(t)**).

Porumbescu discloses claim 4: The method of claim 3, further comprising: creating a set of parametric changes in the first mathematical relation and the second mathematical relation (**Fig 4; col: 4 line: 46; col: 6 line: 25-29; col: 7 line: 43-46**); and

producing a simulated biological attribute based on at least one parametric change from the set of parametric changes, the simulated biological attribute being substantially consistent with at least one biological attribute associated with a reference pattern of diabetes (**col: 4 line: 49-57;**

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col: 5 line: 10-14; Figure 2 item "COMPARISON" and text which further expands on the figure's features).

Porumbescu discloses claim 5: The method of claim 3, further comprising: creating a set of parametric changes in the first mathematical relation and a set of parametric changes in the second mathematical relation,

the set of parametric changes in the first mathematical relation being associated with a first diabetes defect having its own degree of severity (**col: 8 line: 14-17: patient's degree of insulin resistance**),

the set of parametric changes in the second mathematical relation being associated with a second diabetes defect having its own degree of severity (**col: 8 line: 10-13; col: 7 line: 43-46**).

Porumbescu discloses claim 6: The method of claim 3, further comprising: converting at least one biological variable from the group of the first mathematical relation or second mathematical relation into a biological variable that evolves over time (**col: 7 line: 54 to col: 8 line: 17: $I(t)$; col: 4 line: 58-65**); and

producing a series of simulated biological attributes based on the converted biological variable, the series of simulated biological attributes being substantially consistent with a corresponding biological attribute associated with a reference pattern of diabetes, the series of simulated biological attributes representing the disease progression in the reference pattern of diabetes (**col: 7 line: 54 to col: 8 line: 17: $I(t)$**).

Porumbescu discloses claim 7: A computer model of a disease state of diabetes, comprising: a computer-readable memory storing:

instructions defining a set of biological processes related to the disease state of diabetes (**col: 6 line: 5-9, col: 1 line: 41-45; col: 7 line: 1-12; col: 1 line: 41-45; col: 4 line: 46**),

at least two biological processes from the set of biological processes being associated with a set of mathematical relationships related to interactions among biological variables associated with

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the biological processes (**Fig 2 item "MATHEMATICAL MODEL" and text which further expands on the figure's features; Fig 4; col: 7 line: 54 to col: 8 line: 9 I(t)),**
the instructions defining a simulation of glucose metabolism (**col: 3 line: 64 to col: 4 line: 6;**
Fig 2 (computer); col: 3 line: 36-45),

wherein the simulation comprises a representation of two macronutrient metabolisms selected from the group consisting of fat metabolism, protein metabolism and carbohydrate metabolism (**col: 9 line: 20-27; col: 7 line: 26-31; col: 6 line: 25-29; col: 5 line: 36-38; col: 5 line: 64-67; col: 2 line: 35-40; Fig 3 and text which further expands on its features with emphasis on time course);**

and a processor coupled to the computer-readable memory, the processor configured to execute the instructions (**inherent within the reference).**

Porumbescu discloses claim 8: The computer model of claim 7, wherein, upon execution of the instruction, the processor is configured to produce a simulated biological attribute for the disease state of diabetes, the simulated biological attribute is substantially consistent with at least one biological attribute associated with a reference pattern of diabetes (**col: 4 line: 49-57; col: 6 line: 42-56; col: 4 line: 66 to col: 5 line: 49 with emphasis on col: 5 line: 10-14; col: 4 line: 49-57; col: 5 line: 10-14; Figure 2 item "COMPARISON" and text which further expands on the figure's features).**

Porumbescu discloses claim 9: The computer model of claim 7, wherein the instructions further define a set of defects associated with diabetes, the set of defects including a first defect and a second defect, the first defect is a modification of a first biological process from the set of biological processes, the first biological process is related to biological attributes of diabetes in a reference pattern of diabetes (**col: 1 line: 35-38; Fig 2 item "MATHEMATICAL MODEL" and text which further expands on the figure's features; Fig 4; col: 7 line: 54 to col: 8 line: 9 I(t)),** the second defect is a modification of the first biological process or a second biological process from the set of biological processes, the second biological process is related to biological attributes of diabetes in the reference pattern of diabetes (**col: 8 line: 18-30 PE(t); col: 7**

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line: 13-31 EG(t)).

Porumbescu discloses claim 24: A method for creating a computer model of diabetes, comprising:
receiving a plurality of user-selected indications to define a plurality of biological processes

(Porumbescu: col: 8 line: 14-17: patient's degree of insulin resistance; col: 8 line: 10-13; col: 7 line: 43-46),

each biological process from the plurality of biological processes being based on data that relates to changes in biological states to biological attributes of diabetes **(col: 6 line: 5-9, col: 1 line: 41-45),**

wherein the plurality of biological processes comprises a representation of two macronutrient metabolisms selected from the group consisting of fat metabolism, protein metabolism and carbohydrate metabolism **(col: 9 line: 20-27; col: 7 line: 26-31; col: 6 line: 25-29; col: 5 line: 36-38; col: 5 line: 64-67; col: 2 line: 35-40; Fig 3 and text which further expands on its features);**

producing a representation of the plurality of biological processes based on the user-selected indications, the plurality of biological processes defining at least one portion of the disease state of diabetes **(col: 7 line: 1-12; col: 1 line: 41-45; col: 4 line: 46: parameters of interest);**
producing a simulated biological attribute associated with at least one biological attribute of diabetes based on the combined plurality of biology processes **(col: 7 line: 1-12; col: 1 line: 41-45; col: 4 line: 46: parameters of interest);** and

assessing a validity of the computer model based on a comparison between the simulated biological attribute and a corresponding biological attribute associated with a reference pattern of diabetes **(col: 4 line: 49-57; col: 5 line: 10-14; Figure 2 item "COMPARISON" and text which further expands on the figure's features).**

Porumbescu discloses claim 29: The method of claim 1, wherein the simulation comprises a representation of carbohydrate metabolism and a representation of fat metabolism or protein metabolism **(col: 7 line: 1-12; col: 1 line: 41-45; col: 4 line: 46: parameters of interest).**

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Porumbescu discloses claim 30: The method of claim 1, wherein the simulation comprises a representation of carbohydrate metabolism, fat metabolism and protein metabolism (**col: 7 line: 1-12; col: 1 line: 41-45; col: 4 line: 46: parameters of interest**).

Porumbescu discloses claim 31: The computer model of claim 7, wherein the simulation comprises a representation of carbohydrate metabolism and a representation of fat metabolism or protein metabolism (**col: 7 line: 1-12; col: 1 line: 41-45; col: 4 line: 46: parameters of interest**).

Porumbescu discloses claim 32: The computer model of claim 7, wherein the simulation comprises a representation of carbohydrate metabolism, fat metabolism and protein metabolism (**col: 7 line: 1-12; col: 1 line: 41-45; col: 4 line: 46: parameters of interest**).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 10-18, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porumbescu, and further in view of Brown et al's "The global diabetes model: user friendly version 3.0" ("Brown").

As per claim 10, Porumbescu discloses a computer-readable medium having computer-readable instructions stored thereon that, upon execution by a processor, cause the processor to model a disease state of diabetes, the instructions comprising: defining a normal biological state through a set of biological processes, each biological process from the set of biological processes having its own

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associated parameter set (**col: 4 line: 49-57; col: 6 line: 42-56; col: 4 line: 66 to col: 5 line: 49 with emphasis on col: 5 line: 10-14**), the set of biological processes being related to glucose metabolism (**col: 3 line: 64 to col: 4 line: 6; Fig 2 (computer); col: 3 line: 36-45**), wherein the set of biological processes comprises a representation of two macronutrient metabolisms selected from the group consisting of fat metabolism, protein metabolism and carbohydrate metabolism (**col: 9 line: 20-27; col: 7 line: 26-31; col: 6 line: 25-29; col: 5 line: 36-38; col: 5 line: 64-67; col: 2 line: 35-40; Fig 3 and text which further expands on its features with emphasis on time course**); providing a plurality of defect indicators (**col: 6 line: 1-4 ... user input**);

Porumbescu however does not expressly disclose the features enumerated below, which are taught below by an analogous diabetes simulation system disclosed Brown:

providing a plurality of predefined defect indicators each predefined defect indicator from the plurality of predefined defect indicators being uniquely associated with a defect from a plurality of defects associated with a disease state of diabetes, each defect from the plurality of defects being associated with at least one biological process from the set of biological processes (**Brown: Fig 2 "eye disease" "kidney disease" and texts which further expand on their features**); and

receiving a user-specified identification of a first defect indicator from the plurality of predefined defect indicators, a first defect from the plurality of defects being associated with the first defect indicator, the parameter set associated with each biological processes that is associated with the first defect being changed based on the user-specified identification (**page s27 col 1 para 3**). It would have been obvious to one of ordinary skill in the art <diabetes simulation> at the time of Applicant's invention to combine the references in order to have a more realistic simulation of diabetes and allow the patient to easily select their condition from a presented list.

Porumbescu discloses claim 11: The computer-readable medium of claim 10, wherein the instructions further comprise: determining at least one simulated biological attribute based on the modified biological process associated with the first defect, the simulated biological attribute being substantially consistent

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with at least one corresponding biological attribute associated with diabetes in a reference pattern of diabetes (**col: 4 line: 49-57; col: 6 line: 42-56; col: 4 line: 66 to col: 5 line: 49 with emphasis on col: 5 line: 10-14; col: 5 line: 10-14. The comparison is made when indication such as "heads up" and "in or out of control" are presented to the user. These indications are based on the reference points of diabetes and compared to the simulated values).**

As per claim 12, Porumbescu discloses all limitations of claim 10. Porumbescu however does not expressly disclose receiving a user-specified identification of a second defect indicator from the plurality of predefined defect indicators, a second defect from the plurality of defects being associated with the second defect indicator, the parameter set associated with each biological processes that is associated with the second defect being changed based on the user-specified identification. Brown however discloses the said features (**page s27 col 1 para 3**). It would have been obvious to combine the references for the reasons recited above.

Porumbescu discloses claim 13: The computer-readable medium of claim 12, wherein: the first defect has an associated severity based on the change to the at least one associated parameter set (**Porumbescu: col: 8 line: 14-17: patient's degree of insulin resistance**); and

the second defect has an associated severity based on the change to the at least one associated parameter set, the severity associated with the first defect being different from the severity associated with the second defect (**col: 8 line: 10-13; col: 7 line: 43-46**);).

As per claim 14, note the rejection of claim 13 above. The Instant Claim is functionally equivalent to the above-rejected claim and therefore rejected under same prior-art teachings. See section titled "Duplicate Claims", above.

Porumbescu discloses claim 15: The computer-readable medium of claim 10, wherein the instructions further comprise:

producing a simulated biological attribute based on the parameter set associated with each biological processes that is associated with the first defect, the simulated biological attribute being substantially consistent with biological attributes of a reference pattern of diabetes (**col: 4**

line: 49-57; col: 5 line: 10-14; Figure 2 item "COMPARISON" and text which further expands on the figure's features).

As per claim 16, note the rejection of claim 10 above. The Instant Claim is functionally equivalent to the above-rejected claim and therefore rejected under same prior-art teachings but for the Instant Claim has a second defect indicator. Brown discloses this feature in Fig 2 and texts which further expand on its features. Specifically, kidney disease and eye disease correlate to the first and second defect indicators. Porumbescu discloses claim 17: The computer-readable medium of claim 16, wherein: the first defect having an associated severity based on the change to the at least one associated parameter set

(Porumbescu: col: 8 line: 14-17: patient's degree of insulin resistance),

the second defect having an associated severity based on the change to the at least one associated parameter set, the severity associated with the first defect being different from the severity associated with the second defect **(col: 8 line: 10-13; col: 7 line: 43-46).**

Porumbescu discloses claim 18: The computer-readable medium of claim 16, wherein the instructions further comprise:

defining a normal biological state through the set of biological processes, each biological process from the set of biological processes being associated with its own parameter set **(col: 4 line: 49-57; col: 6 line: 42-56; col: 4 line: 66 to col: 5 line: 49 with emphasis on col: 5 line: 10-14).**

Porumbescu discloses claim 33: The computer-readable medium of claim 10, wherein the set of biological processes comprises a representation of carbohydrate metabolism, protein metabolism and fat metabolism **(col: 9 line: 20-27; col: 7 line: 26-31; col: 6 line: 25-29; col: 5 line: 36-38; col: 5 line: 64-67; col: 2 line: 35-40; Fig 3 and text which further expands on its features).**

Porumbescu discloses claim 34: The computer-readable medium of claim 16, wherein the set of biological processes comprises a representation of carbohydrate metabolism, protein metabolism and fat metabolism **(col: 9 line: 20-27; col: 7 line: 26-31; col: 6 line: 25-29; col: 5 line: 36-38; col: 5 line: 64-67; col: 2 line: 35-40; Fig 3 and text which further expands on its features).**

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15. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Porumbescu, and further in view of Brown et al's "The global diabetes model: user friendly version 3.0" ("Brown") and further in view of Official Notice taken.

As per claim 19, Porumbescu all limitations of claim 16. Porumbescu also discloses accounting to patient's degree of insulin resistance (**col: 8 line: 14-17**). Insulin resistance is associated with type 2 diabetes. Porumbescu however does not expressly disclose that the plurality of defects are associated with type 2 diabetes. Official Notice is taken with respect to this limitation. Type 2 diabetes accounts for the vast majority of people with diabetes, 90% to 95%. It would have been obvious to one of ordinary skill in the art <diabetes / disease simulation> at the time of Applicant's invention to combine the references in order to not be limited to the simulation of a single type of diabetes and therefore have a greater market appeal.

16. Claims 20, 25-28, and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lehmann's "Focus on Interactive Educational Diabetes Simulators: Future possibilities" (**Supplied by Applicants in an IDS after Office Action**), and further in view of Porumbescu (**US 6,582,366**).

As per claim 20, Lehmann discloses a diabetes simulator. Lehmann however does not expressly disclose the features enumerated below, which are taught below by an analogous diabetes simulation system disclosed Porumbescu:

A computer-readable medium having computer-readable instructions stored thereon that, upon execution by a processor, cause the processor to model a disease state of diabetes (**inherent within the reference**), the instructions comprising: defining a plurality of biological processes related to a disease state of diabetes wherein the plurality of biological processes comprises a representation of two macronutrient metabolisms selected from the group consisting of fat metabolism, protein metabolism and carbohydrate metabolism (**col: 7 line: 1-12; col: 1 line: 41-45; col: 4 line: 46: parameters of interest; col: 9 line: 20-27; col: 7 line: 26-31; col: 6 line: 25-29; col: 5 line: 36-38; col: 5 line: 64-67; col: 2 line: 35-40; Fig 3 and text which further expands on its features with emphasis on time course**), the step of

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defining including: defining a set of mathematical relations associated with a first biological process from the plurality of biological processes and associated with interactions among biological variables associated with the first biological process (**Fig 2 item "MATHEMATICAL MODEL" and text which further expands on the figure's features; Fig 4; col: 7 line: 54 to col: 8 line: 9 $I(t)$**), and defining a set of mathematical relations associated with a second biological process from the plurality of biological processes and associated with interactions among biological variables associated with the second biological process (**col: 8 line: 18-30 $PE(t)$; col: 7 line: 13-31 $EG(t)$**), a first biological process from the plurality of biological processes being associated with metabolism of at least two from the group of carbohydrates, fats and proteins, a second biological process from the plurality of biological processes being associated with metabolism of glucose (**col: 9 line: 20-27; col: 7 line: 26-31; col: 6 line: 25-29; col: 5 line: 36-38; col: 5 line: 64-67; col: 2 line: 35-40; Fig 3 and text which further expands on its features**). It would have been obvious to one of ordinary skill in the art <diabetes / disease simulation> at the time of Applicant's invention to combine the references in order to have a simulation that is able to be adapted through the use of mathematical functions and variables thus be realistic and help the individual predict what effects will occur under specified condition.

As per claim 25, Lehmann discloses a diabetes simulator. Lehmann however does not expressly disclose the features enumerated below, which are taught below by an analogous diabetes simulation system disclosed Porumbescu: identifying data relating to diabetes, the data relating changes in biological states to biological attributes of diabetes (**col: 6 line: 5-9, col: 1 line: 41-45**);

identifying a plurality of biological processes related to the data, the plurality of biological processes defining at least one portion of the disease state of diabetes (**col: 7 line: 1-12; col: 1 line: 41-45; col: 4 line: 46: parameters of interest**); and combining the plurality of biological processes to form a simulation of at least one biological attribute of diabetes wherein the simulation comprises a representation of fat metabolism (**col: 9**

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line: 20-27; col: 7 line: 26-31; col: 6 line: 25-29; col: 5 line: 36-38; col: 5 line: 64-67; col: 2 line: 35-40; Fig 3 and text which further expands on its features).

It would have been obvious to one of ordinary skill in the art <diabetes / disease simulation> at the time of Applicant's invention to combine the references for the reasons provided above.

As per claim 26, Lehmann discloses a diabetes simulator. Lehmann however does not expressly disclose the features enumerated below, which are taught below by an analogous diabetes simulation system disclosed Porumbescu:

identifying data relating to diabetes, the data relating changes in biological states to biological attributes of diabetes (**col: 6 line: 5-9, col: 1 line: 41-45**);

identifying a plurality of biological processes related to the data, the plurality of biological processes defining at least one portion of the disease state of diabetes (**col: 7 line: 1-12; col: 1 line: 41-45; col: 4 line: 46: parameters of interest**); and

combining the plurality of biological processes to form a simulation of at least one biological attribute of diabetes wherein the simulation comprises a representation of protein metabolism (**col: 9 line: 20-27; col: 7 line: 26-31; col: 6 line: 25-29; col: 5 line: 36-38; col: 5 line: 64-67; col: 2 line: 35-40; Fig 3 and text which further expands on its features**).

It would have been obvious to one of ordinary skill in the art <diabetes / disease simulation> at the time of Applicant's invention to combine the references for the reasons provided above.

As per claim 27, Lehmann discloses a diabetes simulator. Lehmann however does not expressly disclose the features enumerated below, which are taught below by an analogous diabetes simulation system disclosed Porumbescu:

a computer-readable memory storing:

instructions defining a set of biological processes related to the disease state of diabetes, at least two biological processes from the set of biological processes being associated with a set of mathematical relationships related to interactions among biological variables associated with the biological processes, the instructions defining a simulation of at least one biological attribute of

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diabetes wherein the simulation comprises a representation of fat metabolism (**Fig 2 item "MATHEMATICAL MODEL" and text which further expands on the figure's features; Fig 4; col: 7 line: 54 to col: 8 line: 9 I(t); col: 3 line: 64 to col: 4 line: 6; Fig 2 (computer); col: 3 line: 36-45; col: 9 line: 20-27; col: 7 line: 26-31; col: 6 line: 25-29; col: 5 line: 36-38; col: 5 line: 64-67; col: 2 line: 35-40; Fig 3 and text which further expands on its features**); and

a processor coupled to the computer-readable memory, the processor configured to execute the instructions (**col: 6 line: 5-9, col: 1 line: 41-45; col: 7 line: 1-12; col: 1 line: 41-45; col: 4 line: 46**).

It would have been obvious to one of ordinary skill in the art <diabetes / disease simulation> at the time of Applicant's invention to combine the references for the reasons provided above.

As per claim 28, Lehmann discloses a diabetes simulator. Lehmann however does not expressly disclose the features enumerated below, which are taught below by an analogous diabetes simulation system disclosed Porumbescu:

a computer-readable memory storing:

instructions defining a set of biological processes related to the disease state of diabetes, at least two biological processes from the set of biological processes being associated with a set of mathematical relationships related to interactions among biological variables associated with the biological processes, the instructions defining a simulation of at least one biological attribute of diabetes wherein the simulation comprises a representation of protein metabolism (**Fig 2 item "MATHEMATICAL MODEL" and text which further expands on the figure's features; Fig 4; col: 7 line: 54 to col: 8 line: 9 I(t); col: 3 line: 64 to col: 4 line: 6; Fig 2 (computer); col: 3 line: 36-45; col: 9 line: 20-27; col: 7 line: 26-31; col: 6 line: 25-29; col: 5 line: 36-38; col: 5 line: 64-67; col: 2 line: 35-40; Fig 3 and text which further expands on its features**); and

a processor coupled to the computer-readable memory, the processor configured to execute the instructions (**col: 6 line: 5-9, col: 1 line: 41-45; col: 7 line: 1-12; col: 1 line: 41-45; col: 4 line: 46**).

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It would have been obvious to one of ordinary skill in the art <diabetes / disease simulation> at the time of Applicant's invention to combine the references for the reasons provided above.

As per claim 35, Lehmann discloses all limitations of claim 25, Lehmann however does not expressly disclose that the simulation further comprises a representation of carbohydrate metabolism or protein metabolism. Porumbescu however discloses an analogous diabetes simulation system comprising the said features (**col: 9 line: 20-27; col: 7 line: 26-31; col: 6 line: 25-29; col: 5 line: 36-38; col: 5 line: 64-67; col: 2 line: 35-40; Fig 3 and text which further expands on its features**). It would have been obvious to one of ordinary skill in the art <diabetes / disease simulation> at the time of Applicant's invention to combine the references for the reasons provided above.

As per claim 36, Lehmann discloses all limitations of claim 26, Lehmann however does not expressly disclose that the simulation further comprises a representation of carbohydrate metabolism or fat metabolism. Porumbescu however discloses an analogous diabetes simulation system comprising the said features (**col: 9 line: 20-27; col: 7 line: 26-31; col: 6 line: 25-29; col: 5 line: 36-38; col: 5 line: 64-67; col: 2 line: 35-40; Fig 3 and text which further expands on its features**). It would have been obvious to one of ordinary skill in the art <diabetes / disease simulation> at the time of Applicant's invention to combine the references for the reasons provided above.

As per claim 37, Lehmann discloses all limitations of claim 27, Lehmann however does not expressly disclose that the simulation further comprises a representation of carbohydrate metabolism or protein metabolism. Porumbescu however discloses an analogous diabetes simulation system comprising the said features (**col: 9 line: 20-27; col: 7 line: 26-31; col: 6 line: 25-29; col: 5 line: 36-38; col: 5 line: 64-67; col: 2 line: 35-40; Fig 3 and text which further expands on its features**). It would have been obvious to one of ordinary skill in the art <diabetes / disease simulation> at the time of Applicant's invention to combine the references for the reasons provided above.

As per claim 38, Lehmann discloses all limitations of claim 28, Lehmann however does not expressly disclose that the simulation further comprises a representation of carbohydrate metabolism or fat metabolism. Porumbescu however discloses an analogous diabetes simulation system comprising the said

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features (**col: 9 line: 20-27; col: 7 line: 26-31; col: 6 line: 25-29; col: 5 line: 36-38; col: 5 line: 64-67; col: 2 line: 35-40; Fig 3 and text which further expands on its features**). It would have been obvious to one of ordinary skill in the art <diabetes / disease simulation> at the time of Applicant's invention to combine the references for the reasons provided above.

17. Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lehmann's "Focus on Interactive Educational Diabetes Simulators: Future possibilities" (**Supplied by Applicants in an IDS after Office Action**), and further in view of Porumbescu (**US 6,582,366**), and further in view of Brown et al's "The global diabetes model: user friendly version 3.0" ("Brown").

As per claim 21, Lehmann in combination with Porumbescu disclose: The computer-readable medium of claim 20, wherein the instructions further comprise:

defining a set of parametric changes for a first biological process (**Porumbescu: Fig 4; col: 4 line: 46; col: 6 line: 25-29; col: 7 line: 43-46**). Lehmann and Porumbescu however do not expressly disclose receiving a user-specified identification of a first defect indicator from a plurality of predefined defect indicators, the first defect indicator from the plurality of defect indicators being uniquely associated with a first defect from a plurality of defects that is associated with a disease state of diabetes, the set of parametric changes being changed based on the user-specified identification. Brown however discloses an analogous diabetes simulation system having the said feature (**Brown: Fig 2 "eye disease" "kidney disease" and texts which further expand on their features; page s27 col 1 para 3**). It would have been obvious to one of ordinary skill in the art <diabetes simulation> at the time of Applicant's invention to combine the references in order to have a more realistic simulation of diabetes and allow the patient to easily select their condition from a presented list.

As per claim 22, Lehmann and Porumbescu disclose all limitations of claim 21. They however do not expressly disclose the features enumerated below, which are taught by an analogous diabetes simulation by Brown: receiving a user-specified identification of a second defect indicator from the plurality of predefined defect indicators, the second defect indicator from the plurality of defect indicators being

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uniquely associated with a second defect from the plurality of defects that is associated with the disease state of diabetes, the second defect being associated with at least one biological process and its associated parameter set, the at least one parameter set associated with the second defect being changed based on the user-specified identification (**Brown: Fig 2 "eye disease" "kidney disease" and texts which further expand on their features; page s27 col 1 para 3; page s27 col 1 para 3**),

the first defect having an associated severity based on the change to the at least one associated parameter set, the second defect having an associated severity based on the change to the at least one associated parameter set, the severity associated with the first defect being different from the severity associated with the second defect (**Porumbescu: col: 8 line: 14-17: patient's degree of insulin resistance; col: 8 line: 10-13; col: 7 line: 43-46**). It would have been obvious to combine the references for the reasons recited above.

As per claim 23, Lehmann and Porumbescu fully disclose claim 20 and:

receiving a user selection of a link representation from a set of, each link representation in the set of link representations being associated with a different mathematical relationship, the user-selected link representation being associated with the interrelationship between a first biological variable and a second biological variable (**Porumbescu: col: 8 line: 14-17: patient's degree of insulin resistance; col: 8 line: 10-13; col: 7 line: 43-46**), a first link representation from the set of link representations being a representation of the first biological variable having an effect on the second biological variable, a second link representation from the set of link representations being a representation of instances of the first biological variable being converted to instances of the second biological variable (**Porumbescu: Fig 2 item "MATHEMATICAL MODEL" and text which further expands on the figure's features; Fig 4; col: 7 line: 54 to col: 8 line: 9 $I(t)$; col: 8 line: 18-30 $PE(t)$; col: 7 line: 13-31 $EG(t)$**).

It would have been obvious to combine Lehmann and Porumbescu for the reasons stated above.

They do not however expressly teach the features enumerated below which are fully disclosed by

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Brown's analogous diabetes simulation system:

predefined link representations (**Brown: Fig 2 "eye disease" "kidney disease" and texts which further expand on their features**). It would have been obvious to combine Lehmann, Porumbescu and Brown for the reasons stated above.

Conclusion

18. All claims are rejected.

19. The Instant Application is not currently in condition for allowance.

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Furthermore, Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 7/03/06 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b) and MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Silver whose telephone number is (571) 272-8634. The examiner can normally be reached on Monday thru Friday, 10am to 6:30pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kamini Shah can be reached on 571-272-2279. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application

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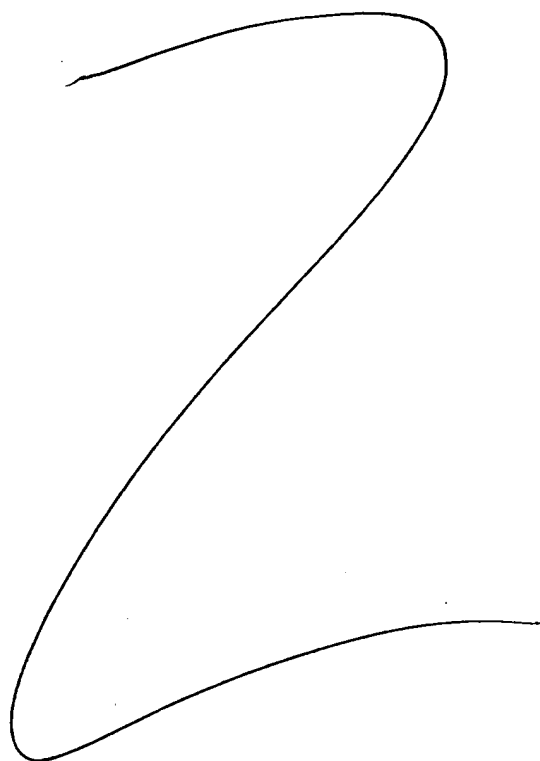
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